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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,486	TSAKAS, SPYROS C.	
	Examiner	Art Unit	
	Thai-An N Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☒ Claim(s) 1-9 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/6/02 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-9 are pending and under current examination.

Priority

Applicants' claim for priority to PCT/GR00/00028, filed 9/27/00 and the Greek application 990100331, filed 9/29/99 is denied. The inventive entity in the PCT application is not the same as the instant application. If Applicants wish to change the inventive entity, Applicants are directed to 37 C.F.R. 1.497(d), which states, in part:

If the oath or declaration filed pursuant to 35 U.S.C. 371(c)(4) and this section names an inventive entity different from the inventive entity set forth in the international application, or if a change to the inventive entity has been effected under PCT Rule 92 bis subsequent to the execution of any oath or declaration which was filed in the application under PCT Rule 4.17(iv) or this section and the inventive entity thus changed is different from the inventive entity identified in any such oath or declaration, applicant must submit:

(1) A statement from each person being added as an inventor and from each person being deleted as an inventor that any error in inventorship in the international application occurred without deceptive intention on his or her part;

(2) The processing fee set forth in § 1.17(i); and

(3) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b) of this chapter); and

(4) Any new oath or declaration required by paragraph (f) of this section.

Note that Applicants must direct this information to PCT Legal Office, not the Examiner.

Claim Objections

Claims 3-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative only and cannot depend from any other multiple dependent claim.. See MPEP § 608.01(n).

Claims 1-9 are objected to because of the following: the claims are more than one sentence. Appropriate correction is required.

Claim 4 is objected to for the following: the claim recites the term "criminololical" in part (c) of the claim. This is not a standard English term. Appropriate correction is required.

Claim 9 is objected to for the following: the claim fails to provide an article for the biological compound. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is unclear. The claim recites that the amniotic cells are taken from amniotic fluid, "which surrounds the human embryo at the early stages of its development" in lines 1-2 of the claim. Amniotic fluid is found throughout the development of the human embryo. The claim recites that the amniotic cells are

taken from amniotic fluid, and are preserved, "after birth and after their natural destruction." It is unclear how cells can be preserved after they are destroyed, as there would not be cells left to preserve. The claim further states that the cells "may be" multiplied, cryopreserved without being multiplied, or multiplied following cryopreservation [see lines 5-9]. This step provides no active steps, and the metes and bounds of "may be" are not clear, do these steps actually occur or not? Claims 3-9 depend from claim 1.

Claim 2 is unclear. Firstly, the claim recites that the amniotic cells are taken from "human body cells". Amniotic cells are exclusive to amniotic fluid, only produced during development. The claim further states that the amniotic cells are taken "through the creation of those of embryo – clone, younger or older than the age of 14 days." See lines 2-3 of the claim. This is unclear, because the metes and bounds of "younger or older than 14 days" cannot be determined – for example, this encompasses an adult human (who would be older than 14 days). It is unclear what the claim is stating in lines 4-5 of the claim that the amniotic cells are preserved "in a viable – useful state after the end of the life of the embryo – clone." What is a viable/useful state? How is this useful after the end of the life of an embryo? How does a clone relate to this claim? The claim further states that the cells "may be" multiplied, cryopreserved without being multiplied, or multiplied following cryopreservation [see lines 5-9]. This step provides no active steps, and the metes

and bounds of "may be" are not clear, do these steps actually occur or not? Claims 3-9 depend from claim 2.

Claim 2 recites the limitation "their cryopreservation" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 is unclear. The claim recites that the compositions contain "a number" of amniotic cells. The metes and bounds of "a number" is unclear. Furthermore, the claim states that the compounds "make the amniotic cells able for long cryopreservation". How do these compounds make the amniotic cells able? Claims 4-9 depend from claim 3.

Claim 4 is unclear. The claim states that the amniotic cells at a point "posterior" to their natural loss and destruction are "used at any time". The term posterior provides a time frame (*i.e.,* later in time) and thus, they cannot be used "at any time". The claim recites that the amniotic cells can be used "for the application of them on genetic identification," in part (b) of the claim. It is unclear what this means. Part (c) is unclear. It recites that the amniotic cells are used to establish any kind of genetic identities data for succession and "criminololical" purposes. It is unclear what succession or criminololical purposes are. Claims 5-9 depend from claim 4.

Claim 5 is unclear. The claim recites that the cells offer a "collective ready" sample in line 1 of the claim. It is unclear what a "collective ready" sample is.

Claim 6 is unclear. Part (b) of the claim recites that the cells can be used for "substituting the ones which suffer failures". This is unclear what "the ones which suffer failures" refers to. Claims 7-9 depend from claim 6.

Claim 7 is confusing. The claim recites, "cell lines categories" and it is unclear what this refers to. Claims 8-9 depend from claim 7.

Claim 8 is improper because the claim recites that the amniotic cells are used "in the future". Appropriate correction is required. Claim 9 depends from claim 8.

Claim 9 is confusing because it states that the biological compound is directly or indirectly produced from amniotic cells, or a bi-product or any biological product produced by the amniotic cells, under the same or different form. Therefore, it is unclear what the claim is directed to because it does not limit the biological compound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene *et al.* [In Vitro, 9(3):156-9 (1973)].

Greene teaches that human amniotic fluid samples were obtained and then the fluids were centrifuged and the cells resuspended in 5 ml of culture. See p. 156, 2nd column. They teach that concentrations of amnion cell cultures between 5 x 10^3 to 1 x 10^4 cells per ml can be used to establish cell cultures. See p. 157, 1st column, *Results* section, 1st ¶. The amnion cell cultures were then frozen using DMSO or glycerol. See Table 1, and p. 157, 2nd column, 2nd full ¶. Accordingly, Greene anticipate the claimed invention.

Note that the claims recite intended uses for the claimed amniotic cells, for example, that they are useful for the creation of differentiated cell lines, and to produce tissues. Intended use does not impart patentable weight to the product. MPEP §2111.02 states, "[I]n apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136, USPQ 458, 459 (CCPA 1963). It is further noted that, "Where the claimed and prior art products are identical or substantially identical in structure or compositions, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation **or obviousness** has been established. MPEP 2112.01 states:

> In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products

> do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)

Furthermore, reliance upon inherency is not improper even though a rejection is based on Section 103 instead of 102. *In re Skoner,* 517 F.2d 947, 186 USPQ 80 (CCPA 1975).

Furthermore, some of the instant claims are product-by-process claims. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Further, see MPEP §2113, "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Pentz *et al.* [**J. of Med. Genetics**, 17:472-475 (1980)].

Pentz teaches the collection of amniotic fluid cells and the consequent freezing of the cells in DMSO. See p. 472, *Materials & Methods*.

Accordingly, Pentz anticipates the claimed invention.

Claims 1, 2, 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Elwan *et al.* [**NeuroReport**, 8:3435-34638 (1997)].

Elwan teach that human amniotic epithelial cells were obtained [see *Materials and Methods*, p. 3435] and tested for the presence, synthesis and release of catecholamines [see *Abstract*]. It was found that the cells expressed norepinephrine, dopamine and DOPAC [see p. 3436, *Results and Discussion*, and Figure 1].

Accordingly, Elwan teach the claimed invention.

Claims 1, 2, 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rebello *et al.* [**Prenatal Diagnosis**, 11:41-46 (1991)].

Rebello teach the collection of amniotic fluid samples, and then the collection of amniotic fluid cells by centrifugation. DNA was then extracted from the amniotic

cell pellets. See p. 42, *Materials and Methods*. The extracted DNA was then analyzed by PCR. See p. 42-43.

Accordingly, Rebello anticipate the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

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